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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,088	10/02/2001	Edwin C. Gravereaux	71417/55062	9526

21874 7590 12/19/2003

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EXAMINER	
KAPUST, RACHEL B	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,088	GRAVEREAUX ET AL.	
	Examiner	Art Unit	
	Rachel B. Kapust	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *5,9,23,25,28,29, and 38* is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claims 5, 9, 23, 25, 28, 29, and 38 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 22-30, in part, drawn to a method for inducing formation of new lymphatic vessels by administering VEGF or a fragment thereof, classified in class 514, subclass 2.

II. Claims 10-12, 23-25, and 28-30, in part, drawn to a method for preventing or reducing the severity of lymphatic vessel damage comprising exposing a mammal to invasive manipulation that damages lymphatic vessels, classified in class 424, subclass 9.2.

III. Claims 10, 11, 13, 14, and 23-30, in part, drawn to a method for preventing or reducing the severity of lymphatic vessel damage comprising exposing a mammal to a disease that damages lymphatic vessels, classified in class 424, subclass 9.2.

IV. Claims 10, 11, 15, 23-25, and 28-30, in part, drawn to a method for preventing or reducing the severity of lymphatic vessel damage comprising exposing a mammal to trauma that damages lymphatic vessels, classified in class 424, subclass 9.2.

V. Claims 10, 11, 16-18, 23-25, and 28-30, in part, drawn to a method for preventing or reducing the severity of lymphatic vessel damage wherein the mammal has a genetic predisposition that damages lymphatic vessels, classified in class 424, subclass 9.2.

VI. Claims 10, 11, 19-21, 23-25, and 28-30, in part, drawn to a method for preventing or reducing the severity of lymphatic vessel damage wherein the mammal has congenital lymphatic vessel damage, classified in class 424, subclass 9.2.

VII. Claims 31-35, drawn to a pharmaceutical product comprising VEGF-2, classified in class 530, subclass 350.

VIII. Claims 36-39, drawn to an animal model for identifying compounds that reduce lymphedema, classified in class 800, subclass 9.

IX. Claim 40, drawn to the VEGFR-3 cDNA sequence, classified in class 435, subclass 69.1.

X. Claim 41, drawn to the VEGFR-3 amino acid sequence, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Group I is distinct from Groups II-VI because the methods are drawn to different conditions and different method steps and thus have different outcome measures and goals. Group I and Groups VII-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups VII and X can be used in a variety of methods such as purification assays, preparing antibodies, ligand binding assays, or other diagnostic assays. The animal model of Group VIII can be used for raising antibodies or in other diagnostic assays. The polynucleotide of Group IX can be used in purification assays, ligand binding assays, or other diagnostic assays.

Group II is distinct from Groups III-VI because the methods are drawn to different conditions and different method steps and thus have different outcome measures. Group II and Groups VII, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups VII and X can be used in a variety of methods such as purification assays, preparing antibodies, ligand binding assays, or other diagnostic

assays. The animal model of Group VIII can be used for raising antibodies or in other diagnostic assays. The polynucleotide of Group IX can be used in purification assays, ligand binding assays, or other diagnostic assays.

Group III is distinct from Groups IV-VI because the methods are drawn to different conditions and different method steps and thus have different outcome measures. Group III and Groups VII, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups VII and X can be used in a variety of methods such as purification assays, preparing antibodies, ligand binding assays, or other diagnostic assays. The animal model of Group VIII can be used for raising antibodies or in other diagnostic assays. The polynucleotide of Group IX can be used in purification assays, ligand binding assays, or other diagnostic assays.

Group IV is distinct from Groups V and VI because the methods are drawn to different conditions and different method steps and thus have different outcome measures. Group IV and Groups VII, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups VII and X can be used in a variety of methods such as purification assays, preparing antibodies, ligand binding assays, or other diagnostic assays. The animal model of Group VIII can be used for raising antibodies or in other diagnostic assays. The polynucleotide of Group IX can be used in purification assays, ligand binding assays, or other diagnostic assays.

Group V is distinct from Group VI because the methods are drawn to different conditions and different method steps and thus have different outcome measures. Group V and Groups VII, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups VII and X can be used in a variety of methods such as purification assays, preparing antibodies, ligand binding assays, or other diagnostic assays. The animal model of Group VIII can be used for raising antibodies or in other diagnostic assays. The polynucleotide of Group IX can be used in purification assays, ligand binding assays, or other diagnostic assays.

Group VI and Groups VII, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups VII and X can be used in a variety of methods such as purification assays, preparing antibodies, ligand binding assays, or other diagnostic assays. The animal model of Group VIII can be used for raising antibodies or in other diagnostic assays. The polynucleotide of Group IX can be used in purification assays, ligand binding assays, or other diagnostic assays.

Groups VII-X are not related. The polypeptides of Groups VII and X are composed of amino acids linked in peptide bonds that are arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domains). The animal model of Group VIII is a composition made up of structurally and functionally complex biological systems. The polynucleotide of Group IX is composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. Furthermore, Group VII is not related to Group X. The amino acid sequence encoding the protein of Group VII is structurally different from the amino acid sequence of the protein of Group X.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the searches required for the different groups are dissimilar from each other, restriction for examination purposes as indicated is proper.

Claims 10 and 11 link inventions II-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 10 and 11. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (703) 305-0634. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm. Please note for your records that as of approximately January 20, 2004, the examiner's new telephone number will be (571) 272-0886.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK
12/16/03

JANET ANDRES
PATENT EXAMINER